REMARKS

In the above-identified Office Action, the Examiner has required that the abstract be corrected. By the above amendment, Applicant has attended to this matter and this requirement is considered obviated. In addition, claims 23-26 have been objected to as being substantially duplicate of claim 7. As noted by the Examiner it is proper, after allowing one claim, to object to the others being a substantial duplicate of the allowed claim. Accordingly, Applicant does not believe that such an objection to be proper in as much as no claims have yet been allowed. Accordingly, Applicant will take no action with regard to claim 23-26 at this time.

The Examiner has rejected claims 1-3, 5-7, 13-15, and 17-22 under 35 U.S.C. §112 as indefinite. By the above amendment, Applicant has corrected this matter, replacing "consisting of" with "containing." As such, Applicant believes the claims are now acceptable.

Claims 1-3, 5-7, 13-14, 17-18, 20, 22 and 23 have been rejected as unpatentable over Welling et al. in view of Sheiness. The Examiner has stated that it would have been obvious to use the method for detecting the presence of bacteria, based on Gram-stain as taught by Welling with a step of using lysis buffer for characterizing Gram-stain of a bacterium and as by Sheiness developing a sensitive method of detection of a bacterium in a sample.

The latest pronouncement concerning obviousness from the Court of Appeals for the Federal Circuit is set forth in Medichem V. S.A. Rolabo S.L., 77 U.S.P.Q. 2nd 1864, at 1869, which makes it clear that hindsight is to be avoided; thus, "to prevent hindsight invalidation of patent claims, the law requires 'some teaching, suggestion or reason' to combine cited references." The Examiner has not pointed to any "teaching, suggestion, or reason" to combine the cited references and merely stated that the ordinary artisan would have a reasonable expectation of success to make such combinations. Without a suggestion from the references themselves, Applicant believes that the hindsight view of the Examiner cannot be sustained.

In the present case, the inventors have provided a new simple and robust way to easily type any bacterial sample using *in situ* hybridization.

The passage in Welling et al. (WO 97/05282) referred to by the Examiner mentions that the "poor permeability of these cells is not solely due to their gram positive nature." In the present invention, it was found bacteria that have morphological similarity can be identically treated chemically. One of the differences of the art with the present invention is that the invention provides a protocol for a wide range of bacteria based on their appearance in a Gram-staining. The art at best mentions protocols for individual genera, which protocols are not the same as the protocols of the invention. The concept of the invention is not apparent from the cited references. Indeed, on page 14, lines 5-8, Welling et al. teach that the bacteria of the *genus lactobacillus* need to be treated with a lysis buffer containing lysozyme and lipase. The present invention differs in that no lipase is present in the lysis buffers. Thus, Welling et al. teaches away from the present invention in that it points to a different composition of the lysis-buffer when compared to the lysis buffers of the present invention.

Combining the reference with Sheiness (U.S. Patent No. 5,700,636) does not overcome Welling's deficiences, as Sheiness also does not teach a general concept and does not teach the lysis buffers of the present invention. The paragraph bridging columns 10 and 11 show describes a "gold standard" lysis buffer containing various enzymes among which lysozyme and lipase (column 10, line 65). Thus Sheiness teaches away from the present invention towards a lysis buffer that contains at least lysozyme and lipase at the lysis enzymes. The combination of Welling et al. and Sheiness et al. therefore cannot result in the invention recited in the present claim 1.

It would also appear that, in the above-noted rejection, the Examiner is picking and choosing from the prior art only so much as supports his position, to the exclusion of other parts necessary to the full appreciation of what these references fairly suggest to one of ordinary skill in the art. Such is not acceptable under *In re* Wesslaw, 147 U.S.P.Q. 391, 393, and others. It is therefore respectfully submitted that claim 1 is not obvious over the combination of Welling and Sheiness.

That the lysis buffer in Sheiness contains the enzymes as stated in the paragraph comes from the fact that they do not detect bacteria but rather bacterial DNA. Sheiness is not interested in detecting intact bacteria. Instead they detect the DNA that is released into solution (summary of the invention in column 6). They do not perform *in situ* hybridization. The artisan in the field of *in situ* hybridization would not turn to Sheiness when looking for lysis protocols, as the goal in *in situ* hybridization differs completely from Sheiness goal.

The Examiner mentions that the ordinary practitioner would have been motivated to combine the method of Welling et al. with the inclusion of lysis buffer (Office Action; page 5, middle of the page). However, when combining the two references the practitioner would have arrived at a completely different lysis buffer, as mentioned above.

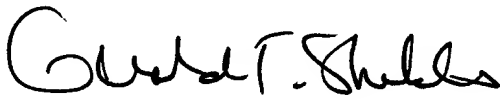
With respect to the rejection of claims 15, 19, 21, 24-25 in view of Welling et al., Sheiness et al. in combination with Hogan (U.S. Patent No. 5,603,460) it is submitted that Hogan does not teach the specific probes of the mentioned claims. Furthermore, Hogan is not concerned with *in situ* hybridization. Again, the intricacies of the difference between normal and *in situ* hybridization are ignored. The observation that a probe performs well in the context of a normal hybridization in the absence of any non-nucleic acid material does not mean that the same probe is suited for *in situ* hybridization, as other purposes and other characteristics of the probe, such as general stickiness and secondary structure are also important.

The Examiner refers to Aller, 105 U.S.P.Q. 233 and 235 to support the argument that, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. It is respectfully submitted that the general conditions of claim 1 were not disclosed in the prior art, nor is the invention routine optimization. The cited art is not concerned with a coherent, simple and robust method that can reliably detect a wide range of bacteria using *in situ* hybridization. Moreover, none of the references use the outcome of a Gram-staining to determine the hybridization protocol to be used. In addition, none of the references use the same lysis buffers as those mentioned in claim 1.

Applicant hereby requests reconsideration and reexamination thereof.

With the above amendments and remarks, this application is considered ready for allowance and Applicant earnestly solicits an early notice of same. Should the Examiner be of the opinion that a telephone conference would expedite prosecution of the subject application, he is respectfully requested to call the undersigned at the below-listed number.

Respectfully submitted,
WELSH & KATZ, LTD.



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Date: **September 13, 2006**
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